

Attorney Docket No.: INT-0004
Inventors: Mattern et al.
Serial No.: 10/002,653
Filing Date: October 19, 2001
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This listing of the claims will replace all prior versions and listings of claims in the application:

Listing of the claims:

Claim 1: (canceled)

Claim 2: (previously presented) The scaffold or matrix of claim 13 further comprising a silicone layer applied to the collagen and glycosaminoglycan co-precipitate prior to cross-linking.

Claim 3: (previously presented) A terminally sterilized matrix or scaffold comprising the scaffold or matrix of claim 13 terminally sterilized by electron beam irradiation.

Claim 4: (previously presented) A terminally sterilized matrix or scaffold comprising the scaffold or matrix of claim 2 terminally sterilized by electron beam irradiation.

Claim 5: (previously presented) A method for producing the scaffold or matrix of claim 13 comprising:

(a) adding glycosaminoglycan to a collagen solution to co-precipitate collagen fibrils coated with glycosaminoglycan from the solution; and

(b) cross-linking the collagen and glycosaminoglycan co-precipitate with glutaraldehyde at a density of cross-linkage

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and under conditions which stabilize the scaffold or matrix toward electron beam radiation at about 15 to about 80 kGy so that the matrix or scaffold retains characteristics to function as a structural support for cell and tissue ingrowth.

Claim 6: (previously presented) The method of claim 5 wherein cross-linking of the collagen and glycosaminoglycan co-precipitate is performed with glutaraldehyde at a concentration greater than 0.25%.

Claim 7: (previously presented) The method of claim 5 wherein the collagen and glycosaminoglycan co-precipitate is subjected to two or more glutaraldehyde cross-linking steps.

Claim 8: (original) The method of claim 7 wherein the two or more cross-linking steps are performed with glutaraldehyde at 0.25%.

Claim 9: (previously presented) A method for producing a terminally sterilized matrix or scaffold comprising:

- (a) producing a scaffold or matrix of claim 13;
- (b) sealing the composition in a package; and
- (c) exposing the composition in the sealed package to electron beam radiation.

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Claim 10: (canceled)

Claim 11: (original) A terminally sterilized matrix or scaffold produced in accordance with the method of claim 9.

Claim 12: (original) A method for regenerating dermal or sub-dermal tissue in a subject comprising applying to or implanting within the subject the terminally sterilized matrix or scaffold of claim 3 at or near an excision site of dermal or subdermal tissue or a site where augmentation of dermal or subdermal tissue is required.

Claim 13: (previously presented) A scaffold or matrix comprising a collagen and glycosaminoglycan co-precipitate cross-linked with glutaraldehyde at a density of cross-linkage and under conditions which stabilize the scaffold or matrix toward electron beam radiation at about 15 to about 80 kGy so that the matrix or scaffold retains characteristics to function as a structural support for cell and tissue ingrowth.

Claim 14: (previously presented) The scaffold of claim 13 wherein the conditions of cross-linkage comprise glutaraldehyde in an acetic acid solution.

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Claim 15: (previously presented) The method of claim 5 wherein the conditions of cross-linkage comprise glutaraldehyde in an acetic acid solution.

Claim 16: (previously presented) The method of claim 6 wherein the glutaraldehyde concentration is 0.5%.

Claim 17: (new) A scaffold or matrix comprising a lyophilized collagen and glycosaminoglycan co-precipitate and a silicone layer applied to the lyophilized collagen and glycosaminoglycan co-precipitate, said lyophilized collagen and glycosaminoglycan co-precipitate cross-linked after application of the silicone layer with glutaraldehyde at a density of cross-linkage and under conditions which stabilize the scaffold or matrix toward electron beam radiation at about 15 to about 80 kGy so that the matrix or scaffold retains characteristics to function as a structural support for cell and tissue ingrowth.

Claim 18: (new) A method for producing the scaffold or matrix of claim 17 comprising:

(a) adding glycosaminoglycan to a collagen solution to co-precipitate collagen fibrils coated with glycosaminoglycan from the solution;

(b) lyophilizing the collagen and glycosaminoglycan co-precipitate of step (a);

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- (c) applying a silicone layer to the lyophilized co-precipitate of step (b); and
- (d) cross-linking the lyophilized collagen and glycosaminoglycan co-precipitate with glutaraldehyde at a density of cross-linkage and under conditions which stabilize the scaffold or matrix toward electron beam radiation at about 15 to about 80 kGy so that the matrix or scaffold retains characteristics to function as a structural support for cell and tissue ingrowth.

Claim 19: (new) A method for producing a terminally sterilized matrix or scaffold comprising:

- (a) producing a scaffold or matrix comprising a collagen and glycosaminoglycan co-precipitate cross-linked with glutaraldehyde at a density of cross-linkage and under conditions which stabilize the scaffold or matrix toward electron beam radiation at about 15 to about 80 kGy so that the matrix or scaffold retains characteristics to function as a structural support for cell and tissue ingrowth;
- (b) sealing the composition in a package; and
- (c) exposing the composition in the sealed package to electron beam radiation.

Claim 20: (new) A terminally sterilized matrix or scaffold produced in accordance with the method of claim 19.